

REMARKS

The present Request for Continued Examiner is submitted in response to the Advisory Action of April 30, 2004, which was issued by the Examiner in response to the Response After Final Rejection submitted April 22, 2004 pursuant to 37 CFR 1.116 in response to the Final Official Action mailed February 25, 2004. The Applicant respectfully requests granting of the Request for Continued Examination and entry of the present Preliminary Amendment, which includes the amendments and arguments originally submitted in the Response After Final Rejection before reconsideration of this Application.

Claims 1, 2 and 4-11 were pending in the Application at the time of the Final Office Action and, after entry of the present Preliminary Amendment, amended claims 2, 4, 5, 7-10 and 12 and new claims 13-16 will be pending in the present Application.

At the time of the Final Office Action, the Examiner had declared claim 10 to contain allowable subject matter, for which the Applicant thanks the Examiner, and the Examiner had rejected claims 1, 11, 2, 7-9, 4, 5 and 6 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the reasons noted in the official action. The Applicant has considered the Examiner's grounds for rejection of the claims under 35 U.S.C. § 112 and has addressed these issues in the submitted claim amendments in so far as applicable in light of other amendments to the claims. The Applicant therefore respectfully requests that the Examiner reconsider and withdraw all rejections of the claims under 35 U.S.C. § 112 and the allowance of the claims as amended herein.

Also at the time of the Final Office Action, the Examiner had also rejected claims 1, 11, 2, 7-9, 4 and 5 under 35 U.S.C. § 103(a), as being unpatentable over Marsoner et al. '157 in view of Berger et al. '314 in view of Applicant's statement in view of Ito '028. The Applicant acknowledges and respectfully traverses the raised obviousness rejection in view of the following remarks.

The Applicant notes that claims 1-9 and 11, which had been rejected under 35 U.S.C. § 103 over the cited prior art, includes the basic recitations and limitations of

claim 10, but without the limitations concerning the structure the analyzer mechanism in which the sensor modules are employed. The Applicant respectfully disagrees with the Examiner concerning the rejections of claims 1-9 and 11, however, and believes that the subject matter of claims 1-9 and 11, which are directed to a sensor module alone, defines an allowable invention.

Upon further consideration of the present invention as described in the specification and drawings of the present Application and the Examiner's grounds for rejection of claims 1-9 and 11, the Applicant has amended claims 1, 2, 4-6, 9 and 11 by canceling claims 1, 6 and 11, making claims 2, 4, 5, 9 dependent from allowed claim 10, and thereby allowable as dependent from an allowed claim, and replacing claim 1 with new claim 12 with claims 7 and 8 being amended to be dependent from new claim 12.

It will be apparent that new claim 12 is based upon claim 1 and falls within the recitations and limitations of claim 1 but is directed to a specific embodiment of the sensor module of the present invention, thereby further accentuating the distinctions between the present invention as recited in claim 12 and the cited prior art.

Considering new independent claim 12 in further detail, it will be noted that the specific embodiment recited in new claim 12 is fully described in the specification and drawings as originally filed, as well as being encompassed in the recitations of the original and amended versions of claim 1. In particular, the Applicant would refer the Examiner to Figs. 8D, 8E, 8F, 8G, 8I and 8J and the corresponding paragraphs [0129] through [0136] of the specification.

As described, new claim 12 is directed to a sensor module for performing analysis tests on fluid samples wherein the sensor module is formed of a sensor module body having a single, unitary fluid passage extending between an input passage and an output passage of the module body and forming a flow path for conducting fluids through the sensor module. The sensor module further includes a plurality of film sensor elements located on a single substrate that is located in the fluid passage and wherein the sensor elements include both a plurality of film sensors for performing measurements of a fluid sample flowing through the

sensor chamber and a reference electrode positioned in the fluid passage for performing reference measurements. The sensor module also includes a record memory that is external to the fluid passage and that stores information relevant to the plurality of film sensors.

The embodiment recited in claim 12 therefore incorporates a plurality of film sensors and a reference sensor, or electrode, into a single, unitary fluid passage enclosed in the sensor module body wherein, as illustrated in Fig. 8E, for example, the fluid passage forms a single sensor chamber containing all of the film sensors and the reference sensor and wherein all of the film sensors and the reference sensor are located directly in the fluid flow.

It will also be noted that the Applicant has also added new claims 13, 14, 15 and 16 that new claims 13-16 are based upon previously existing ones of claims 1-11, but are made dependent on claim 12 in the same manner in which the original claims were dependent on claim 1 and are subsequently dependent on claim 10.

It will also be seen that the Applicant has made other, minor amendments to the present claims to clarify certain of the terms and recitations therein, all of which are supported by the claims and specification as originally filed.

Next considering the prior art references cited by the Examiner, and first considering Marsoner et al. '157, Marsoner et al. '157 describes a "unit" 4, that is, a sensor chamber, comprised of a plurality of cells 5 containing sensor electrodes and interconnected through a channel 6 that is narrow with respect to cells 5 and that has a stub channel 7 branching off from channel 6 to hold a reference electrode.

It will be seen that there are fundamental distinctions between the present invention and the teachings of Marsoner et al. '157. For example, in Marsoner et al. '157 the sensors are individually located in cells that are interconnected through a channel that is of substantially smaller cross section than are the cells. This arrangement of cells separated by a narrow channel often results in the composition of the fluid sample in each cell varying from cell to cell. This variance in the samples isolated in each cell is due to the restricted flow of fluids through the channel so that the composition of the fluid in each cell will depend, for example, on what

quantities of what fluids have flowed through the individual cells. That is, upon whether the flow of fluids through the channel and the cells been adequate to completely flush a previous fluid from each cell, or is there a remaining residue, and has the flow of fluids been sufficient to prevent the build-up of residues in the cells and an in the channel.

This is, in fact, a problem recognized in Marsoner et al. '157, and Marsoner et al. '157 proposes to address this problem by allowing alternate paths, such as bypass line 9, to flush waste fluids and residues from the cells. Unfortunately, the bypass line 9 proposed by Marsoner et al. '157 does not in fact flush residues through and out of the cells and channel, but instead only avoids the flushing of residues from an input source to the channel from being flushed into the channel.

In basic contrast from the teachings of Marsoner et al. '157, and as specifically recited in new claim 12, the present invention as recited in claim 12 is fully distinguished from and over Marsoner et al. '157 in that the film sensors, including the reference sensor, are located in a single, unitary fluid passage that extends between an input passage and an output passage of the module body and that forms a single chamber that is the flow path for fluids through the sensor module. Therefore, instead of having separate cells separated by constricted lengths of channel, the sensor module of the present invention provides a single chamber that contains all of the sensors and that provides a single, unitary flow path of generally even dimensions. As a result, the flow path through the sensor module of the present invention effectively has no constrictions or obstacles to the flow of fluids through the sensor module and not only do the sensors and reference sensor all receive a fluid having an even composition but any tendency to accumulate residues and wastes in the flow path are significantly reduced.

In addition, it must be noted that Marsoner et al. '157 specifically teaches that the reference electrode 5' will be located out of the flow path through the cells and channel and instead will be located in a stub channel 7 branching off from channel 6. Marsoner et al. '157 expressly states that this separation of the reference electrode from the fluid flow path is necessary to prevent contamination of the flow path by the reference electrode, and to prevent

contamination of the reference electrode by fluids in the flow path. This design, however, can lead to serious errors because the reference electrode is not necessarily in contact with the same fluid of the same composition as the electrodes in the cells.

In this regard, the teachings of Marsoner et al. '157 are in direct conflict with and are directly contrary to the present invention wherein the reference sensor is expressly directly located in the flow path through the sensor module and is expressly located in the same flow passage chamber as the film sensors. This design thereby ensures that the reference sensor is in contact with the same fluid of the same composition as the film sensors, thereby ensuring a more accurate reference.

It is the belief and position of the Applicant that the present invention as recited in new claim 12 is fully distinguished over and from the teachings of Marsoner et al. '157 under the requirements and provisions of 35 U.S.C. § 103. The Applicant respectfully requests that the Examiner reconsider and withdraw all rejections of claim 12 and all claims dependent therefrom over Marsoner et al. '157 under 35 U.S.C. § 103, and the allowance of claim 12 and all claims dependent therefrom.

Next considering the teachings of Berger et al. '314 and Marsoner et al. '157 in view of Berger et al. '314, the Examiner essentially cites Berger et al. '314 as teaching the enclosure of a sensor module as taught by Marsoner et al. '157 within a "sensor chamber" as recited in claim 1 and in other claims of the present Application. The Examiner points out that Marsoner et al. '157 suggests enclosing the Marsoner et al. '157 "unit 4" in some form of heating arrangement in order to heat the fluid samples in the "unit 4" and that Berger et al. '314 teaches a temperature chamber that would be useful for this purpose.

The Applicant respectfully disagrees with the Examiner's position with regard to Berger et al. '314 and Marsoner et al. '157 for the following reasons. First, it must be noted that the purpose of the sensor chamber of the present invention as recited in canceled claim 1 and in allowable claim 10 is to mechanically contain and support the sensor modules and to lock the sensor modules into a sealed configuration with each other and with the analysis

apparatus so that the fluid flow paths through the sensor modules and the analysis apparatus is continuous and fully contains all liquids flowing therein.

In contrast from the sensor chamber of the present Application, the heating apparatus of Marsoner et al. '157 and the heating chamber of Berger et al. '314 do not appear to mechanically support modules or to lock modules into a sealed configuration with each other and with an analysis apparatus, but instead only provide a heated environment for the purposes of the test performed by the Berger et al. '314 apparatus. Further in this regard, it must be noted that Marsoner et al. '157 specifically describes that any sealing between the Marsoner et al. '157 module and other modules or portions of the Marsoner et al. '157 apparatus is accomplished entirely by means of structures built into the modules themselves, and not by means of any structures or mechanisms related to the heating apparatus or heating chamber described by either Berger et al. '314 or Marsoner et al. '157.

In addition, it must be noted that the Berger et al. '314 apparatus is a gas chromatograph and thereby requires the maintenance of a heated environment for the tests performed by the apparatus, and that Marsoner et al. '157 also mentions hearing of the module containing the test electrodes. In contrast, the analysis apparatus of the present invention does not require any form of heating and the specification and drawings in fact do not even mention any form of heating apparatus.

Again, and therefore, the purpose, function and structure of the sensor chamber described in the present Application, and of certain elements of the sensor modules described and claimed in the present Application, is to mechanically contain and support the sensor modules and to lock the sensor modules into a sealed configuration with each other and with the analysis apparatus. Neither Berger et al. '314 or Marsoner et al. '157 teaches or suggests any form of sensor chamber designed to support the sensor modules and to lock the sensor modules into a sealed configuration with each other and with an analysis apparatus.

The combination of Berger et al. '314 in view of Marsoner et al. '157 would teach only that the suggest provision of an external heating apparatus for the Marsoner et al. '157 sensor

module could be met by installing the sensor module in a temperature control chamber as taught by Berger et al. '314, which is not relevant to the present invention.

The combination of Berger et al. '314 in view of Marsoner et al. '157 would not, however, teach or even suggest any form of mechanism or structure to mechanically contain and support the sensor modules and to lock the sensor modules into a sealed configuration with each other and with the analysis apparatus as neither Berger et al. '314 nor Marsoner et al. '157 addresses or even suggests or hints at this type of structural mechanism for this purpose.

It is the belief and position of the Applicant that the present invention as recited in the claims is fully distinguished over and from the teachings of Berger et al. '314 and of Marsoner et al. '157 in view of Berger et al. '314 under the requirements and provisions of 35 U.S.C. § 103. The Applicant respectfully requests that the Examiner reconsider and withdraw all rejections of the claims over Berger et al. '314 or Marsoner et al. '157 in view of Berger et al. '314 under 35 U.S.C. § 103, and the allowance of the claims as amended herein.

Next considering the Applicant's statement regarding the availability of record memories, the Applicant's statement is merely that record memories suitable for the purposes of the invention are commercially available, and the Applicant in fact describes such a record memory in detail. It must be noted, however, that the Applicant does not claim a record memory per se, but instead claims the use of such a record memory together with a film sensor in a sensor module, or, in this instance, with several film sensors in a single sensor module. As such, it is the Applicant's belief and position that while the Applicant's statement is pertinent to the present invention, as in fact it was intended to be for purposes of disclosure of a presently understood best mode of practicing the invention, it was not provided and was not and is not intended to be limiting of the actual invention claimed.

Finally considering the teachings of Ito '028, Ito '028 describes a biosensor containing a biological measurement sensor apparatus and a memory for recording data pertinent to the use of the biosensor.

In contrast from the sensor module of the present invention as recited in claim 12, the Ito '028 biosensor is in itself a complete sensor module, including not only the a sensor but also a reference electrode and a fluid flow path for conducting a fluid through the sensor wherein the fluid flow path includes the means necessary for the biosensor to mechanically mate with another biosensor or an analysis apparatus to form a complete fluid flow path through an analysis apparatus and one or more biosensors.

It must also be noted that the memory in the Ito '028 biosensor module is contained in and is an integral part of the biosensor module and is thus dedicated solely to recording data pertinent to only the single sensor contained in the module. As a consequence, the memory arrangement suggested by Ito '028 does not suggest the structure of the present invention wherein one record memory that is external to the sensors themselves is used to record data pertinent to all of the sensors in the module.

It must also be noted that the reference electrode of the Ito '028 module is likewise contained within and is an integral part of the biosensor module and therefore operates only with respect to the single sensor therein. Again, the reference electrode arrangement suggested by Ito '028 does not suggest the reference electrode structure of the present invention wherein one reference electrode functions as a reference electrode for all of the sensors in the module.

It should also be noted that the Ito '028 module cannot be used to construct a multi-sensor module of the type recited in new claim 12 as the construction of a multi-sensor structure using the Ito '028 modules could be accomplished only by chaining together several Ito '028 modules, each having one sensor. Not only would this result in the use of many more reference electrodes and memories than would be required by a module of the present invention. The chaining of several Ito '028 modules would also result in a structure somewhat similar to that of Marsoner et al. '157 wherein separate sensor chambers are connected but separated by flow channels between the sensors, thus potentially resulting in problems similar to those discussed with regard to the Marsoner et al. '157 arrangement.

The combination of Ito '028 with either or both of Berger et al. '314 or Marsoner et al. '157 is effectively a combination of Ito '028 with Marsoner et al. '157 and, in any case, would not be feasible for a number of reasons. For example, Marsoner et al. '157 describes what is effectively a sealed unit with the leads to the sensor electrodes passing out through the body walls of the Marsoner et al. '157 module. It will be noted, however, that because the Ito '028 includes a sensor plus a reference electrode plus a memory the number of required input/output connections to an Ito '028 module would be far in excess of what would be practical in a Marsoner et al. '157 module. The alternatives would be to eliminate the reference electrode and memory, which negates the purpose of the Ito '028 module, or to simply connect only the sensor leads, which would leave a major part of the circuits in the Ito '028 module unused. It should be further noted that the Ito '028 module places the reference electrode in the flow path, which is contrary to the teachings of Marsoner et al. '157.

The combination of Berger et al. '314 in view of Marsoner et al. '157 in view of Ito '028 would therefore not teach or even suggest any form of the sensor module of the present invention as recited in new claim 12 for the reasons discussed above. That is, none of the references teach or suggest the elements of the present invention and the teachings of one reference do not compensate for the lack of teachings in another. In addition, it must be recognized that the teachings and requirements of the references are generally incompatible; for example, the use of the Ito '028 sensor in the Marsoner et al. '157 module would result only in a vastly more complex and expensive module with more input/output leads than would be practical and with the reference electrodes located therein in direct contravention to the teachings of Marsoner et al. '157.

It is the belief and position of the Applicant that the present invention as recited in the claims is fully distinguished over and from the teachings of Berger et al. '314, Marsoner et al. '157 and Ito '028 and of Marsoner et al. '157 in view of Berger et al. '314 in view of the Applicant's statement and in view of Ito '028 under the requirements and

provisions of 35 U.S.C. § 103. The Applicant therefore respectfully requests that the Examiner reconsider and withdraw all rejections of the claims over Berger et al. '314, Marsoner et al. '157 and Ito '028 and of Marsoner et al. '157 in view of Berger et al. '314 in view of the Applicant's statement and in view of Ito '028 under 35 U.S.C. § 103, and the allowance of the claims as amended herein.

If any further amendment to this application is believed necessary to advance prosecution and place this case in allowable form, the Examiner is courteously solicited to contact the undersigned representative of the Applicant to discuss the same.

In view of the above amendments and remarks, it is respectfully submitted that all of the raised rejections should be withdrawn at this time. If the Examiner disagrees with the Applicant's view concerning the withdrawal of the outstanding rejections or applicability of the Marsoner et al. '157 and Berger et al. '314 references, the Applicant respectfully requests the Examiner to indicate the specific passage or passages, or the drawing or drawings, which contain the necessary teaching, suggestion and/or disclosure required by case law. As such teaching, suggestion and/or disclosure is not present in the applied references, the raised rejection should be withdrawn at this time. Alternatively, if the Examiner is relying on his/her expertise in this field, the Applicant respectfully requests the Examiner to enter an affidavit substantiating the Examiner's position so that suitable contradictory evidence can be entered in this case by the Applicant.

In view of the foregoing, it is respectfully submitted that the raised rejections should be withdrawn and this application is now placed in a condition for allowance. Action to that end, in the form of an early Notice of Allowance, is courteously solicited by the Applicant at this time.

The Applicant respectfully requests that any outstanding objections or requirements, as to the form of this application, be held in abeyance until allowable subject matter is indicated for this case.

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Respectfully submitted,

Gary D. Clapp, Reg. No. 29,055

Customer No. 020210

Davis & Bujold, P.L.L.C.

Fourth Floor

500 North Commercial Street

Manchester NH 03101-1151

Telephone 603-624-9220

Facsimile 603-624-9229

E-mail: patent@davisandbujold.com

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